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UNITED STATES DEPARTMENT OF COMMERCE
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#15

In re TheraTech Inc.
U.S. Patent No. 4,983,395

: DECISION DENYING
: APPLICATION FOR PATENT
: TERM EXTENSION

On April 17, 1996, an Order to Show Cause was mailed. The order stated that the above-identified patent was not considered eligible for patent term extension because the active ingredient, testosterone, of the product ANDRODERM® had been previously approved for commercial marketing or use by the Food and Drug Administration.

No response has been received to the order.

Accordingly, for the reasons stated in the Order to Show cause, the application for patent term extension, filed November 24, 1995, is denied.

Charles Pearson
Patent Legal Administrator
Office of the Deputy Assistant Commissioner
for Patent Policy and Projects

cc: RONALD L. WILSON, DIRECTOR
HEALTH ASSESSMENT POLICY STAFF
OFFICE OF HEALTH AFFAIRS (HFY-20)
FOOD AND DRUG ADMINISTRATION
5600 FISHERS LANE, ROOM 15-22
ROCKVILLE, MD 20857

RE: ANDRODERM® (testosterone)
FDA DOCKET NO: 95E-0420

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